Jonathan W. Emord (Pro Hac)
Andrea G. Ferrenz (Pro Hac)
Emord & Associates, P.C.
5282 Lyngate Court
Burke, VA 22015
Phone: (202) 466-6937
Fax: (202) 466-6938

Peggy A. Tomsic (3879)
Chris R. Hogle (7223)
Berman, Tomsic & Savage
50 South Main Street, Suite 1250
Salt Lake City, UT 84144
Phone: (801) 328-2200

Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH,

CENTRAL DIVISION

NUTRACEUTICAL CORPORATION, et al., Plaintiffs, v, LESTER CRAWFORD, DVM, Acting Commissioner of the U.S. Food and Drug Administration, et al., Defendants.	**PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT** **(Oral Argument Requested)** Case No. 2:04CV00409 TC

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiffs Nutraceutical Corporation and Solaray, Inc. (hereinafter "Plaintiffs") move this Honorable Court to: (1) enter summary judgment in plaintiffs' favor on their first four causes of action; (2) enjoin the

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Defendants from enforcing their "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk," 69 Fed. Reg. 6788 (February 11, 2004)(hereinafter "Final Rule") against Plaintiffs' sale of a low dose ephedrine-containing dietary supplement (i.e., one containing less than 10 mg of ephedrine alkaloids per daily dose); and (3) remand the matter to the Food and Drug Administration ("FDA") for further rulemaking consistent with the Court's opinion.

Plaintiffs' motion is based on the following grounds:

1. The Final Rule violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321 et seq.; hereinafter "FDCA"), which incorporates the Dietary Supplement Health and Education Act (21 U.S.C. § 342), because it bans the sale of dietary supplements containing 10 mg or less of ephedrine alkaloids per daily dose even though FDA did not prove, by a preponderance of the evidence, that such dietary supplements present a significant or unreasonable risk of illness or injury, as required by the FDCA. Instead of satisfying its burden of proof under the FDCA, FDA invented a more lenient standard that is unsupported by, and contrary to, the FDCA.

2. The Final Rule violates the Administrative Procedure Act (5 U.S.C. § 701 et seq.; hereinafter "APA"), because the Final Rule is arbitrary, capricious and otherwise contrary to law.

3. The Final Rule violates the APA because it adopts and applies a new test to evaluate dietary supplements–a risk/benefit assessment–without giving required notice and an opportunity for public comment.

For these reasons, explained in detail in the accompanying Memorandum of Points and Authorities, Plaintiffs respectfully request that this Honorable Court grant this motion. Accompanying this motion is the Affidavit of Chris R. Hogle in Support of Motion for Summary Judgment.

DATED this 17th day of August, 2004.

Respectfully submitted,

SOLARAY, INC. AND
NUTRACEUTIAL CORPORATION

By: _____

Jonathan W. Emord
Andrea G. Ferrenz
Karl M. Nobert
Emord & Associates, P.C.
5282 Lyngate Court
Burke, VA 22015
Phone: (202) 466-6937
Fax: (202) 466-6938
jemord@emord.com

By: 

Peggy A. Tomsic
Chris R. Hogle
Berman, Tomsic & Savage
50 South Main Street, Suite 1250
Salt Lake City, UT 84144
Phone: 328-2200

CERTIFICATE OF SERVICE

I hereby certify that I caused a true and correct copy of the within and foregoing PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT to be mailed, postage prepaid, this 18th day of August, 2004, to the following:

Paul M. Warner, United States Attorney
Jan N. Allred, Assistant United States Attorney
185 South State Street, Suite 400
Salt Lake City, UT 84111
Attorneys for Defendants